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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
0609.4820002

APPLICATION NO.
09/672,020

APPLICANT
Gardella *et al.*

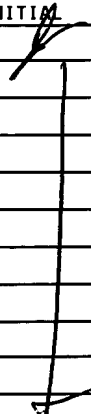
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September 29, 2000




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	AA1	4,086,196	04/25/1978	Tregear	260	112.5 R	03/28/1975
	AB1	4,698,328	10/06/1987	Neer <i>et al.</i>	514	12	12/05/1986
	AC1	4,736,866	04/12/1988	Leder <i>et al.</i>	800	1	06/22/1984
	AD1	4,761,406	08/02/1988	Flora <i>et al.</i>	514	86	06/06/1985
	AE1	5,393,869	02/28/1995	Nakagawa <i>et al.</i>	530	324	02/28/1995
	AF1	5,501,979	03/26/1996	Geller <i>et al.</i>	435	320.1	11/30/1993
	AG1	5,656,465	08/12/1997	Panicali <i>et al.</i>	435	172.3	05/04/1994
	AH1	5,693,616	12/02/1997	Krstenansky <i>et al.</i>	514	12	05/23/1995
	AI1	5,723,577	03/03/1998	Dong	530	324	03/29/1996
	AJ1	5,763,416	06/09/1998	Bonadio <i>et al.</i>	514	44	02/18/1994
	AK1	5,836,905	11/17/1998	Lemelson <i>et al.</i>	604	21	12/27/1996

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1 ✓	EP 0 477 885 A2	04/01/1992	Europe	1		Yes No
	AM1 ✓	WO 92/17581	10/15/1992	WIPO			
	AN1 ✓	EP 0 561 412 A1	09/22/1993	Europe	1		Yes No
	AO1 ✓	WO 95/11988	05/04/1995	WIPO			
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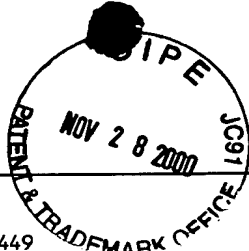
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	AR ✓	1	Altschul, S.F., <i>et al.</i> , "Basic Local Alignment Search Tool," <i>J. Mol. Biol.</i> 215:403-410, Academic Press (1990)
	AS ✓	1	Azarani, A., <i>et al.</i> , "Structurally Diverse N-terminal Peptides of Parathyroid Hormone (PTH) and PTH-related Peptide (PTHrP) Inhibit the Na ⁺ /H ⁺ Exchanger NHE3 Isoform by Binding to the PTH/PTHrP Receptor Type I and Activating Distinct Signaling Pathways," <i>J. Biol. Chem.</i> 271:14931-14936, American Society for Biochemistry and Molecular Biology (1996)
	AT ✓	1	Barbier, J.-R., <i>et al.</i> , "Bioactivities and Secondary Structures of Constrained Analogues of Human Parathyroid Hormone: Cyclic Lactams of the Receptor Binding Region," <i>J. Med. Chem.</i> 40:1373-1380, The American Chemical Society (1997)

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DATE CONSIDERED 6-7-03

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	AA2	5,917,122	06/29/1999	McTiernan <i>et al.</i>	800	18	03/14/1997
	AB2	5,922,927	07/13/1999	Bujard <i>et al.</i>	800	25	07/21/1997
	AC2	5,741,486	04/21/1998	Pathak <i>et al.</i>	424	93.21	06/06/1995
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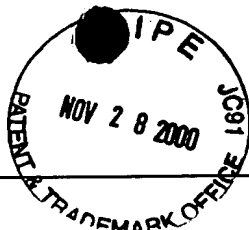
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	AR	2	Bisello, A., <i>et al.</i> . "Parathyroid Hormone-Receptor Interactions Identified Directly by Photocross-linking and Molecular Modeling Studies," <i>J. Biol. Chem.</i> 273:22498-22505, American Society for Biochemistry and Molecular Biology (August 1998)
	AS	2	Born, W., <i>et al.</i> . "Inhibition of Parathyroid Hormone Bioactivity by Human Parathyroid Hormone (PTH)-(3-84) and PTH-(8-84) Synthesized in <i>Escherichia coli</i> ," <i>Endocrinol.</i> 123:1848-1853, The Endocrine Society (1988)
	AT	2	Broadus, A.E., and Stewart, A.F., "Parathyroid Hormone-Related Protein: Structure, Processing and Physiological Actions," in <i>The Parathyroids. Basic and Clinical Concepts</i> , Bilezikian, J.P., <i>et al.</i> , eds., Raven Press, N.Y., pp. 259-294 (1994)

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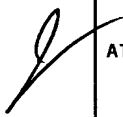
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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR ✓	3	Caulfield, M.P., <i>et al.</i> , "The Bovine Renal Parathyroid Hormone (PTH) Receptor Has Equal Affinity for Two Different Amino Acid Sequences: The Receptor Binding Domains of PTH and PTH-Related Protein Are Located within the 14-34 Region," <i>Endocrinol.</i> 127:83-87, The Endocrine Society (1990)
	AS ✓	3	Cenatiempo, Y., "Prokaryotic gene expression in vitro transcription - translation coupled systems," <i>Biochimie</i> 68:505-515, Elsevier (1986)
	AT ✓	3	Chorev, M., <i>et al.</i> , "Modifications of Position 12 in Parathyroid Hormone and Parathyroid Hormone Related Protein: Toward the Design of Highly Potent Antagonists," <i>Biochem.</i> 29:1580-1586, The American Chemical Society (1990)

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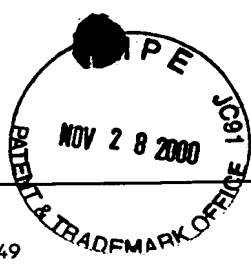
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	AR	4	Cohen, F.E., <i>et al.</i> , "Analogues of Parathyroid Hormone Modified at Positions 3 and 6," <i>J. Biol. Chem.</i> 266:1997-2004, American Society for Biochemistry and Molecular Biology (1991)
	AS	4	Cwirla, S. E., <i>et al.</i> , "Peptide Agonist of the Thrombopoietin Receptor as Potent as the Natural Cytokine," <i>Science</i> 276:1696-1699, American Association for the Advancement of Science (June 1997)
	AT	4	Dong, M., <i>et al.</i> , "Demonstration of a Direct Interaction between Residue 22 in the Carboxyl-terminal Half of Secretin and the Amino-terminal Tail of the Secretin Receptor Using Photoaffinity Labeling," <i>J. Biol. Chem.</i> 274:903-909, American Society for Biochemistry and Molecular Biology (January 1999)

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>5</u>	Fairwell, T., <i>et al.</i> , "Total Solid-Phase Synthesis, Purification, and Characterization of Human Parathyroid Hormone-(1-84)," <i>Biochem. 22</i> :2691-2697, The American Chemical Society (1983)
	AS	<u>5</u>	Gardella, T.J., <i>et al.</i> , "Expression of Human Parathyroid Hormone-(1-84) in <i>Escherichia coli</i> as a Factor X-cleavable Fusion Protein," <i>J. Biol. Chem. 265</i> :15854-15859, American Society for Biochemistry and Molecular Biology (1990)
	AT	<u>5</u>	Gardella, T.J., <i>et al.</i> , "Mutational Analysis of the Receptor-activating Region of Human Parathyroid Hormone," <i>J. Biol. Chem. 266</i> :13141-13146, American Society for Biochemistry and Molecular Biology (1991)

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	AR	6	Gardella, T.J., <i>et al.</i> , "Analysis of Parathyroid Hormone's Principal Receptor-Binding Region by Site-Directed Mutagenesis and Analog Design," <i>Endocrinol.</i> 132:2024-2030, The Endocrine Society (1993)
	AS	6	Gardella, T.J., <i>et al.</i> , "Parathyroid Hormone (PTH)-PTH-related Peptide Hybrid Peptides Reveal Functional Interactions between 1-14 and 15-34 Domains of the Ligand," <i>J. Biol. Chem.</i> 270:6584-6588, American Society for Biochemistry and Molecular Biology (1995)
	AT	6	Goltzmann, D., <i>et al.</i> , "Analysis of the Requirements for Parathyroid Hormone Action in Renal Membranes with the Use of Inhibiting Analogues," <i>J. Biol. Chem.</i> 250:3199-3203, American Society for Biochemistry and Molecular Biology (1975)

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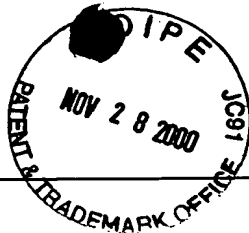
	AR	Z	Gombert, F.O., <i>et al.</i> , "Alanine and D-Amino Acid Scan of Human Parathyroid Hormone," in <i>Peptides: Chemistry, Structure and Biology</i> , Kaumaya, P.T.P. and Hodges, R.S., eds., Mayflower Scientific Ltd., England, UK, pp. 661-662 (1996)
	AS	Z	Gottesman, S., "Bacterial Regulation: Global Regulatory Networks," <i>Ann. Rev. Genet.</i> 18:415-441, Annual Reviews, Inc. (1984)
	AT	Z	Goud, N.A., <i>et al.</i> , Solid-Phase Synthesis and Biologic Activity of Human Parathyroid Hormone(1-84)," <i>J. Bone Min. Res.</i> 6:781-789, Mary Ann Liebert, Inc. (1991)

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	AR ✓	8	Hoare, S.R.J., <i>et al.</i> . "Measurement of Agonist and Antagonist Ligand-Binding Parameters at the Human Parathyroid Hormone Type 1 Receptor: Evaluation of Receptor States and Modulation by Guanine Nucleotide," <i>J. Pharmacol. Exp. Ther.</i> 289:1323-1333, American Society for Pharmacology and Experimental Therapeutics (June 1999)
	AS ✓	8	Holtmann, M.H., <i>et al.</i> . "Critical Contributions of Amino-terminal Extracellular Domains in Agonist Binding and Activation of Secretin and Vasoactive Intestinal Polypeptide Receptors," <i>J. Biol. Chem.</i> 270:14394-14398, American Society for Biochemistry and Molecular Biology (1995)
	AT J	8	Holtmann, M. H., <i>et al.</i> . "Molecular Basis and Species Specificity of High Affinity Binding of Vasoactive Intestinal Polypeptide by the Rat Secretin Receptor," <i>J. Pharmacol. Exp Ther.</i> 279:555-560, American Society for Pharmacology and Experimental Therapeutics (1996)

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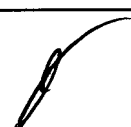
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Horiuchi, N., <i>et al.</i> "A Parathyroid Hormone Inhibitor in vivo: Design and Biological Evaluation of a Hormone Analog," <i>Science</i> 220:1053-1055, American Association for the Advancement of Science (1983)
	AS	2	Izaki, K., "Plasmid Induced Heavy Metal Resistance in Bacteria," <i>Jpn. J. Bacteriol.</i> 33:729-742, Japanese Society for Bacteriology (1978) [in Japanese]
	AT	2	John, Jr., J.F.. and Twitty, J.A.. "Plasmids as Epidemiologic Markers in Nosocomial Gram-Negative Bacilli: Experience at a University and Review of the Literature," <i>Rev. Infect. Dis.</i> 8:693-704, The University of Chicago Press (1986)

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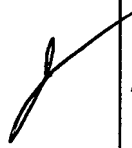
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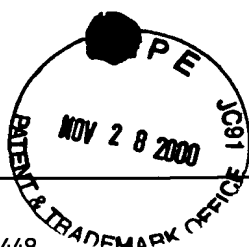
	AR	<u>10</u>	Jüppner, H., <i>et al.</i> , "The Parathyroid Hormone-like Peptide Associated with Humoral Hypercalcemia of Malignancy and Parathyroid Hormone Bind to the Same Receptor on the Plasma Membrane of ROS 17/2.8 cells," <i>J. Biol. Chem.</i> 263:8557-8560, American Society for Biochemistry and Molecular Biology (1988)
	AS	<u>10</u>	Jüppner, H., <i>et al.</i> , "Properties of Amino-Terminal Parathyroid Hormone-Related Peptides Modified at Positions 11-13," <i>Peptides</i> 11:1139-1142, Pergamon Press (1990)
	AT	<u>10</u>	Jüppner, H., <i>et al.</i> , "A G Protein-Linked Receptor for Parathyroid Hormone and Parathyroid Hormone-Related Peptide," <i>Science</i> 254:1024-1026, American Association for the Advancement of Science (1991)

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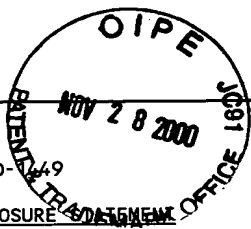
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	AR ✓	<u>11</u>	Karaplis, A.C., <i>et al.</i> , "Lethal skeletal dysplasia from targeted disruption of the parathyroid hormone-related peptide gene," <i>Genes & Develop.</i> 8:277-289, Cold Spring Harbor Laboratory Press (1994)
	AS ✓	<u>11</u>	Kimura, T., <i>et al.</i> , "Discovery of a Novel Thrombopoietin Mimic Agonist Peptide," <i>J. Biochem.</i> 122:1046-1051, The Japanese Biochemistry Society (1997)
	AT ✓	<u>11</u>	Kotin, R.M., <i>et al.</i> , "Site-specific integration by adeno-associated virus," <i>Proc. Natl. Acad. Sci. USA</i> 87:2211-2215, National Academy of Sciences of the USA (1990)

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	✓	12	Kronenberg, H.M., <i>et al.</i> , "Parathyroid Hormone: Biosynthesis, Secretion, Chemistry and Action," in <i>Handbook of Experimental Pharmacology</i> , Volume 107, Mundy, G.R. and Martin, T.J., eds., Springer-Verlag, NY, pp. 507-567 (1993)
	AS	✓	12	Kronenberg, H.M., <i>et al.</i> , "The PTH/PTHrP Receptor: One Receptor for Two Ligands," in <i>Molecular Genetics of Endocrine Disorders</i> , Thakker, R.V., ed., Chapman & Hall Medical, London, UK, pp. 389-420 (1997)
	AT	✓	12	Lanske, B., <i>et al.</i> , "PTH/PTHrP Receptor in Early Development and Indian Hedgehog-Regulated Bone Growth," <i>Science</i> 273:663-666, American Association for the Advancement of Science (1996)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	13	Lebkowski, J.S., <i>et al.</i> , "Adeno-Associated Virus: a Vector System for Efficient Introduction and Integration of DNA into a Variety of Mammalian Cell Types," <i>Mol. Cell. Biol.</i> 8:3988-3996, The American Society for Microbiology (1988)
	AS	13	Li, B., <i>et al.</i> , "Minimization of a Polypeptide Hormone," <i>Science</i> 270:1657-1660, American Association for the Advancement of Science (1995)
	AT	13	Livnah, O., <i>et al.</i> , "Functional Mimicry of a Protein Hormone by a Peptide Agonist: The EPO Receptor Complex at 2.8 Å," <i>Science</i> 273:464-471, American Association for the Advancement of Science (1996)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>14</u>	Luck, M.D., <i>et al.</i> . "The (1-14) Fragment of Parathyroid Hormone (PTH) Activates Intact and Amino-Terminally Truncated PTH-1 Receptors," <i>Molecular Endocrinol.</i> 13:670-680, The Endocrine Society (May 1999)
	AS	<u>14</u>	Majeska, R. J., <i>et al.</i> . "Parathyroid Hormone-Responsive Clonal Cell Lines from Rat Osteosarcoma," <i>Endocrinol.</i> 107:1494-1503, The Endocrine Society (1980)
	AT	<u>14</u>	Mannstadt, M., <i>et al.</i> . "Evidence for a Ligand Interaction Site at the Amino-Terminus of the Parathyroid Hormone (PTH)/PTH-related Protein Receptor from Cross-linking and Mutational Studies," <i>J. Biol. Chem.</i> 273:16890-16896, American Society for Biochemistry and Molecular Biology (July 1998)

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	AR	✓	15	Neugebauer, W., <i>et al.</i> , "Solution Structure and Adenylyl Cyclase Stimulating Activities of C-Terminal Truncated Human Parathyroid Hormone Analogues," <i>Biochem.</i> 34:8835-8842 (1995)
	AS	✓	15	Nissenson, R.A., <i>et al.</i> , "Synthetic Peptides Comprising the Amino-terminal Sequence of a Parathyroid Hormone-like Protein from Human Malignancies," <i>J. Biol. Chem.</i> 263:12866-12871, American Society for Biochemistry and Molecular Biology (1988)
	AT	✓	15	Nussbaum, S. R., <i>et al.</i> , "Parathyroid Hormone • Renal Receptor Interactions," <i>J. Biol. Chem.</i> 255:10183-10187, American Society for Biochemistry and Molecular Biology (1980)

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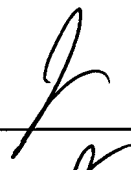
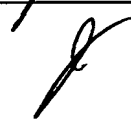
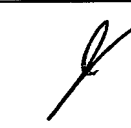
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	AR	16	Plotkin, H., <i>et al.</i> . "Dissociation of Bone Formation from Resorption during 2-Week Treatment with Human Parathyroid Hormone-Related Peptide-(1-36) in Humans: Potential as an Anabolic Therapy for Osteoporosis," <i>J. Clin. Endocrinol. & Metabol.</i> 83:2786-2791, The Endocrine Society (August 1998)
	AS	16	Potts, J.T., <i>et al.</i> , "Structure based design of parathyroid hormone analogs," <i>J. Endocrinol.</i> 154:S15-S21, A Society for Endocrinology Publication (September 1997)
	AT	16	Rixon, R.H., <i>et al.</i> . "Parathyroid Hormone Fragments May Stimulate Bone Growth in Ovariectomized Rats by Activating Adenylyl Cyclase," <i>J. Bone Miner. Res.</i> 9:1179-1189, Mary Ann Liebert, Inc. (1994)

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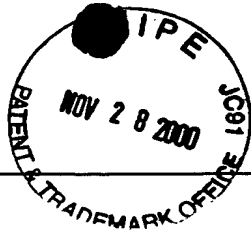
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	AR	17	Roe, E.B., <i>et al.</i> , "Parathyroid Hormone 1-34 (hPTH 1-34) and Estrogen Produce Dramatic Bone Density Increases in Postmenopausal Osteoporosis - Results from a Placebo-Controlled Randomized Trial," <i>J. Bone & Mineral Res.</i> 14:S137, Abstract No. 1019, Blackwell Science, Inc. (September 1999)
	AS	17	Rosenblatt, M., <i>et al.</i> , "Identification of a Receptor-Binding Region in Parathyroid Hormone," <i>Endocrinol.</i> 107:545-550, The Endocrine Society (1980)
	AT	17	Rosenblatt, M., "Parathyroid Hormone: Chemistry and Structure-Activity Relations," in <i>Pathobiology Annual</i> , Volume 11, Joachim, H.L., ed., Raven Press, N.Y., pp. 53-86 (1981)

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	AR	18	Schipani, E., <i>et al.</i> . "Identical Complementary Deoxyribonucleic Acids Encode a Human Renal and Bone Parathyroid Hormone (PTH)/PTH-Related Peptide Receptor," <i>Endocrinol.</i> 132:2157-2165, The Endocrine Society (1993)
	AS	18	Segre, G. V., and Goldring, S. R., "Receptors for Secretin, Calcitonin, Parathyroid Hormone (PTH)/PTH-Related Peptide, Vasoactive Intestinal Peptide, Glucagonlike Peptide 1, Growth Hormone-Releasing Hormone, and Glucagon Belong to a Newly Discovered G-Protein -Linked Receptor Family," <i>Trends in Endo. Metab.</i> 4:309-314, Elsevier Science Publishing Co. (1993)
	AT	18	Seifter, S., and England, S., "Analysis for Protein Modifications and Nonprotein Cofactors," <i>Methods in Enzymol.</i> 182:626-646, Academic Press, Inc. (1990)

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	AR	19	Shen, V., <i>et al.</i> , "Effects of Combined and Separate Intermittent Administration of Low-Dose Human Parathyroid Hormone Fragment (1-34) and 17 β -Estradiol on Bone Histomorphometry in Ovariectomized Rats with Established Osteopenia," <i>Calcif. Tissue Int.</i> 50:214-220, Springer-Verlag New York Inc. (1992)
	AS	19	Shimizu, M., <i>et al.</i> , "Type-Substitution Analysis of the Amino-Terminal Fragment of Parathyroid Hormone, PTH(1-14): An Approach toward New Low Molecular Weight PTH Agonists," <i>J. Bone & Mineral Res.</i> 14(suppl. 1):Abstract No. F398, Mary Ann Liebert, Inc. (September 1999)
	AT	19	Shimizu, M., <i>et al.</i> , "Minimization of Parathyroid Hormone," <i>J. Biol. Chem.</i> 275: 21836-21843, American Society for Biochemistry and Molecular Biology (July 2000)

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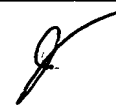
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>20</u>	Slovik, D.M., <i>et al.</i> "Restoration of Spinal Bone in Osteoporotic Men by Treatment With Human Parathyroid Hormone (1-34) and 1,25-Dihydroxyvitamin D," <i>J. Bone Miner. Res.</i> 1:377-381, Mary Ann Liebert, Inc. (1986)
	AS	<u>20</u>	Stroop, S.D., <i>et al.</i> "Chimeric Human Calcitonin and Glucagon Receptors Reveal Two Dissociable Calcitonin Interaction Sites," <i>Biochem.</i> 34:1050-1057, American Chemical Society (1995)
	AT	<u>20</u>	Takasu, H., <i>et al.</i> "Dual Signaling and Ligand Selectivity of the Human PTH/PTHrP Receptor," <i>J. Bone Miner. Res.</i> 14:11-20, American Society for Bone and Mineral Research (January 1999)

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	AR	21	Tregear, G.W., <i>et al.</i> , "Bovine Parathyroid Hormone: Minimum Chain Length of Synthetic Peptide Required for Biological Activity," <i>Endocrinol.</i> 93:1349-1353, The Endocrine Society (1973)
	AS	21	Treager, G.W., and Potts, Jr., J.T., "Synthetic Analogues of Residues 1-34 of Human Parathyroid Hormone: Influence of Residue Number 1 on Biological Potency <i>In Vitro</i> ," <i>Endocrine Res. Comm.</i> 2:561-570, Marcel Dekker, Inc. (1975)
	AT	21	Ureña, P., <i>et al.</i> , "Regulation of Parathyroid Hormone (PTH)/PTH-Related Peptide Receptor Messenger Ribonucleic Acid by Glucocorticoids and PTH in ROS 17/2.8 and OK Cells," <i>Endocrinol.</i> 134:451-456, The Endocrine Society (1994)

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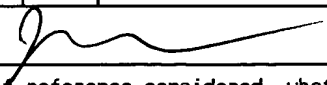
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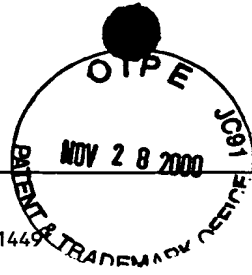
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	AR	22	Usdin, T.B., <i>et al.</i> , "Identification and Functional Expression of a Receptor Selectively Recognizing Parathyroid Hormone, the PTH2 Receptor," <i>J. Biol. Chem.</i> 270:15455-15458, American Society for Biochemistry and Molecular Biology (1995)
	AS	22	Wells, J. A., "Hormone Mimicry," <i>Science</i> 273:449-450, American Association for the Advancement of Science (1996)
	AT	22	Whitfield, J.F., <i>et al.</i> , "Restoration of Severely Depleted Femoral Trabecular Bone in Ovariectomized Rats by Parathyroid Hormone-(1-34)," <i>Calcif. Tissue Int.</i> 56:227-231, Springer-Verlag New York Inc. (1995)
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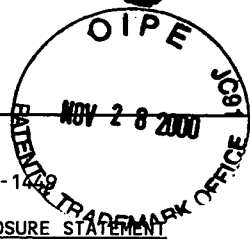
	AR	23	Whitfield, J.F., and Morley, P.. "Small bone-building fragments of parathyroid hormone: new therapeutic agents for osteoporosis," <i>Trends Pharmacol. Sci.</i> 16:372-376, Elsevier Science Ltd. (1995)
	AS	23	Whitfield, J.F., <i>et al.</i> .. "Comparison of the Ability of Recombinant Human Parathyroid Hormone, rhPTH-(1-84), and hPTH-(1-31)NH ₂ to Stimulate Femoral Trabecular Bone Growth in Ovariectomized Rats," <i>Calcif. Tissue Int.</i> 60:26-29. Springer-Verlag New York, Inc. (January 1997)
	AT	23	Wrighton, N.C., <i>et al.</i> .. "Small Peptides as Potent Mimetics of the Protein Hormone Erythropoietin," <i>Science</i> 273:458-463, American Association for the Advancement of Science (1996)

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FORM PTO-1009

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	AO						Yes No
	AP						Yes No

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	AR	24	Dialog, English language abstract of Izaki, K., "Plasmid Induced Heavy Metal Resistance in Bacteria," <i>Jpn. J. Bacteriol.</i> 33:729-742 (1978)
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EXAMINER

DATE CONSIDERED

6-4-07

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.